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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,979	05/16/2005	Takamasa Kato	H6808.0082/P082	1868

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EXAMINER	
ZEMAN, MARY K	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 04/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/534,979	KATO ET AL.	
	Examiner	Art Unit	
	Mary K. Zeman	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) *4-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-8* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of Group I, claims 1-3 in the reply filed on 1/4/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 4-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/4/06.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Copies of the certified documents were forwarded by the International Bureau for this National Stage Application.

Information Disclosure Statement

The IDS statements filed 5/16/05, and 10/11/05 have been entered and considered. The reference BA, the International Preliminary Examination Report, has been lined through, as this is not a published document, and the citation lacks a publication date.

Drawings

The drawings were received on 5/16/05. These drawings are acceptable to the examiner.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to methods of manipulating data. These methods do not meet the limitations of statutory subject matter. The methods do not provide a

physical transformation of one article into another. The methods do not provide a concrete tangible and useful result. The methods merely rearrange data and evaluate the data, and transmit what was obtained. The obtained data is not transformed in any manner, merely "evaluated" then passed on, depending on the evaluation. There is no concrete, tangible and useful result. The method of claim 3 does not even transmit data, but cancels the processing altogether. No result of any kind is obtained. The methods are not clearly computer implemented. They appear to be manipulation of abstract ideas.

To meet section 101 requirements, the claims must be for a practical application of the abstract idea, law of nature, or natural phenomenon. Diehr, 450 U.S. at 187, 209 USPQ at 8 ("application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection."); Benson, 409 U.S. at 71, 175 USPQ at 676 (rejecting formula claim because it "has no substantial practical application").

To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways:

1) The claimed invention "transforms" an article or physical object to a different state or thing.

2) The claimed invention otherwise produces a useful, concrete and tangible result, based on the factors discussed below.

Practical Application That Produces a Useful, Concrete, and Tangible Result

For eligibility analysis, physical transformation "is not an invariable requirement, but merely one example of how a mathematical algorithm [or law of nature] may bring about a useful application." AT&T, 172 F.3d at 1358-59, 50 USPQ2d at 1452... In determining whether the claim is for a "practical application," the focus is not on whether the steps taken to achieve a particular result are useful, tangible and concrete, but rather that the final result achieved by the claimed invention is "useful, tangible and concrete." (1) "USEFUL RESULT" For an invention to be "useful" it must satisfy the utility requirement of section 101. The USPTO's official interpretation of the utility requirement provides that the utility of an invention has to be (i) specific, (ii) substantial and (iii) credible. MPEP § 2107 and Fisher, 421 F.3d at ___, 76 USPQ2d at 1230 (citing the Utility Guidelines with approval for interpretation of "specific" and "substantial"). (2) "TANGIBLE RESULT" The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a § 101 judicial exception, in that the process claim must set forth a practical application of that § 101 judicial exception to produce a real-world result. Benson, 409 U.S. at 71-72, 175 USPQ at 676-77 (invention ineligible because had "no

substantial practical application."). "[A]n application of a law of nature or mathematical formula to a ... process may well be deserving of patent protection." Diehr, 450 U.S. at 187, 209 USPQ at 8 (emphasis added); see also Corning, 56 U.S. (15 How.) at 268, 14 L.Ed. 683 ("It is for the discovery or invention of some practical method or means of producing a beneficial result or effect, that a patent is granted . . ."). In other words, the opposite meaning of "tangible" is "abstract." (3) "CONCRETE RESULT" Another consideration is whether the invention produces a "concrete" result. Usually, this question arises when a result cannot be assured. In other words, the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. In re Swartz, 232 F.3d 862, 864, 56 USPQ2d 1703, 1704 (Fed. Cir. 2000) (where asserted result produced by the claimed invention is "irreproducible" claim should be rejected under section 101). The opposite of "concrete" is unrepeatable or unpredictable.

See also:
http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. For example, in claim 1 (and multiple claims thereafter) the multiple and/or clauses render the actual steps confusing. It is further unclear in claim 1 how positional information can be "in accordance" with request information. The term "accordance" generally means agreement or conformity, and it is unclear how this is applied to the positional and request information. It is further unclear how the other types of information are "corresponding" and it is unclear how those relationships are defined. It is further unclear how one piece of information is "based on" another. Data is merely numbers or information, without the decision making required to link to other data. No conclusions to be made or rule structures are set forth such that any implications can be made. It is unclear what information is ultimately obtained by the claimed method, and it is further unclear what is to be done with it. It

is entirely unclear how to "evaluate" the data, and what the basis of the evaluation requires. When is the information "adequate" and how it is decided? The specification appears to disclose that the adequacy is based on levels of security access and permissions, however, the claims are not that limited and appear to embrace data quality issues such as corrupted files or inaccurate data. The preamble states that this is a method of "processing information" however, nothing is done to the retrieved data such that and "processing" actually take place. Simple retrieval of information based upon a query is not actual processing. Claims 2 and 3 limits claim 1 wherein a set of data is determined to be "adequate" or "inadequate" however, claim 1 never actually makes that decision. The data is merely "evaluated" for adequacy.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Califano (US 2003/ 055824).

The claims are drawn to methods of processing data wherein nucleotide sequence data is obtained and evaluated for transmission based on "flag information", and may or may not be transmitted with associated data. The specification indicated that flag information may relate to security access, and permission levels for access to data. The associated data may be diagnosis data, personal information, etc.

Califano (US 2003/0055824 having priority to at least 6/8/02) discloses methods and systems for tracking and controlling genetic data. Sequence data of patients is stored with varying permission and consent information (paragraph 0010, etc), along with diagnostic and

personal information (paragraph 0008, 0024, etc). (See for example, figure 1 and Figure 3) Requests from doctors can be received (0024, , 0027), the appropriate data obtained and evaluated (0028+), then, if the consent is authorized, the data is transmitted (0034+). If not, no transmission takes place. As such, this document anticipates the claimed invention.

Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Bova (US 6,675,166).

Bova (US 6,675,166 having priority to at least 12/4/00) discloses methods and systems for tracking and controlling genetic data. Sequence data of patients (phenotype and genotype data) is stored with varying permission and consent information (selective access, consent), along with diagnostic and personal information (diagnosis of cancer). Laboratory methods, scientific literature and other references can be linked as "Associated information." Requests from scientists can be received, the appropriate data obtained and evaluated, then, if the consent is authorized, the data is transmitted. If not, no transmission takes place. See also figures 23-24. As such, this document anticipates the claimed invention.

Claims 1-3 are rejected under 35 U.S.C. 102(a and e) as being anticipated by GLAXO Gp LTD (WO 02/12434).

GLAXO (WO 02/12434, published 2/14/02 having priority to at least 8/9/01) discloses methods and systems for tracking and controlling genetic data. Sequence data of patients is stored with varying permission and consent information (page 6), along with diagnostic and personal information (unique label of page 7 is equivalent to flag data of claims, p11,). (See also example 1) Requests from doctors can be received, the appropriate data obtained and evaluated, then, if the consent is authorized, the data is transmitted. If not, no transmission takes place. As such, this document anticipates the claimed invention.

The US National stage application of this International application is US 2004/0029138.

Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Ledley (US 2003/0040002.

Ledley (US 2003/0040002 having priority to at least 8/9/01) discloses methods and systems for tracking and controlling genetic data. Sequence data of patients (genotype, haplotype, karyotype, SNP, marker) is stored with varying permission and consent information (paragraph 0028), along with diagnostic and personal information (disease, disorder, clinical outcome, genetic risk). Requests from doctors (health care providers)can be received, the appropriate data obtained and evaluated (0037, 0040, 0130 etc), then, if the consent is authorized, the data is transmitted (notifying, counseling, re-counseling). If not, no transmission takes place. As such, this document anticipates the claimed invention.

Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Morand (US 2002 0046054).

Morand (US 2002/0046054 having priority to at least 8/27/01)) discloses methods and systems for tracking and controlling genetic data. Samples and sequence data of patients (genomic and proteomic data) is stored with varying permission and consent information (paragraphs 0051-0060), along with diagnostic and personal information (disease, disorder, clinical outcome, genetic risk). Requests from doctors (end users) can be received, the appropriate data obtained and evaluated (cross referencing, security, obtaining consent to transmit), then, if the consent is authorized, the data can be transmitted. If not, no transmission takes place. See also Figures 1 and 2 and their explanations. As such, this document anticipates the claimed invention.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following are documents disclosing secure storage and transmittal of genetic or medical data which are cumulative to the above rejections:

Reinhoff, JR. US 2002/0019746

Michelson US 2002/0002474

Stanton JR 6,673,908 correlates sequence and "sequence related information" to produce a diagnosis.

The following references involve informed consent for DNA sampling/testing:

Knoppers et al. DNA Sampling and Informed Consent. CMAJ 140 May 1, 1989, 1023-1028.

Moutel et al. Bio-libraries and DNA storage.. Med Law (2001) 20:193-204.

Gulcher et al. Protection or privacy by third party encryption in genetic research in Iceland. European Journal of Human Genetics (2000) 8: 739-742.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, PhD can be reached on (571) 272 0718. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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